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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/200,791	11/30/1998	THOMAS M. BEHR	018734/0161	9799

7590 09/10/2002  
FOLEY & LARDNER  
3000 K STREET N W  
WASHINGTON, DC 200075109

EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/10/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/200,791

Applicant(s)

BEHR ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-21, 23-29 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-21, 23-29 and 31-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-9, 11-21, 23-29, 31-37 are pending.  
Claims 10 and 30 have been canceled.  
Claims 1, 12, 18 and 32 have been amended.  
Claims 1-9, 11-21, 23-29, 31-37 are under examination.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

### ***Rejections Withdrawn***

3. The rejection of claims 1-4, 6, 8, 13-14, 18-19, 23-24, 26, 28, 33-34 under 35 U.S.C. 102(b) as being anticipated by Hammond et al (Br. J. Cancer 67:1437-1439, 1993 (IDS #4) as evidenced by U. S. Patent 5,225,180 (issued 7/93) is withdrawn in view of arguments.

### ***Response to Arguments***

4. The rejection of claims 1-9, 11-21, 23-29, 31-37 under 35 U.S.C. 103(a) as being unpatentable over Behr et al (Cancer Research 55:3825-3834, 1995), and further in view of Grey et al (U. S. Patent 5,380,513, issued 1/10/95, IDS #4) and Raines et al (U.S. Patent 5,840,296, filed 10/15/97) is maintained.

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The response filed 7/29/02 has been carefully considered but is deemed not to be persuasive. The response states that the teachings do not provide motivation or a reasonable expectation of success. The response states that a person would know that the unique structure and properties of antibodies as compared to protein conjugates would likely cause difference in the effectiveness of D- and L-isomers of lysine at reducing kidney uptake and a person would not automatically expect that D- and L-lysine would behave similarly because they have dramatically different effects (see page 5 of response) and Grey is directed to L-lysine not D-lysine and Raines fails to disclose D-lysine in a method of reducing renal retention of protein conjugates (see page 6 of response). In response to these arguments, this rejection is based on a combination of references however, the response seems to argue the references separately and in response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to no motivation to combine the references, Behr et al clearly teach the D- and L-lysine were equally effective as was poly-lysine (see abstract) and as taught by Grey the targeting molecules can be proteins with conjugates (see column 5-6) and as such it would have been obvious to use D-lysine given the fact that it is equally effective in reducing renal retention. In addition, Behr et al teach the approach of using D-lysine or L-lysine is a relatively simple approach and can be used to reduce the renal retention of labeled peptides (see page 3833). Thus, there is clear motivation

to combine the teachings of Behr et al, Gray et al, and Raines et al to arrive at the claimed invention.

The response argues that one of ordinary skill in the art would familiar with the teachings of Behr et al would not have expected D-lysine to be effective at reducing the kidney uptake of protein conjugates that are not antibody conjugates and since Gray et al does not disclose D-lysine Gray et al would not have caused a person of ordinary skill in the art to have a greater expectation of success in employing the claimed method (see page 6 of response). In response to these arguments, again Behr et al teach either lysine type was equally effective and the simple approach can be used with protein conjugates. Thus, one skilled in the art would have been motivated and had a reasonable expectation of success because Behr et al teach the method is simple and both lysine compounds were equally effective and can be used with peptide conjugates and in view of Gray who teach protein conjugates and Raines who teaches ribonuclease conjugates it would have been obvious to produce the claimed method.

### ***Conclusion***

5. No claim is allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

  
SHEELA HUFF  
PRIMARY EXAMINER

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703-306-5879